

REMARKS

In the Office Action, the Specification has been objected to; Claim 23 has been objected to; Claims 1-39 are rejected under 35 U.S.C. § 112, second paragraph; and Claim 18 has been rejected under 35 U.S.C. § 103. Claims 10 and 12 have been amended; and claim 23 has been cancelled without prejudice or disclaimer. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, the Patent Office objects to the Specification for alleged informalities. In particular, the Patent Office questions whether the ratio of whey protein to casein protein should be 1:1 and not 7:3 as disclosed in the Specification.

Although the ratio of 1:1 is illustrative of one example of the ratio of whey protein to casein protein according to an embodiment of the present invention, the ratio of 7:3 (70:30) is clearly supported in the specification. As disclosed in the Specification, on page 3 at lines 15-18, the ratio of whey protein to casein protein can be about 60:40 to 70:30, most preferably 70:30. Thus, nowhere does the Specification suggest that the ratio of 7:3 (i.e., 70:30) should be substituted with the ratio of 1:1 as the Patent Office seems to suggest. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

In the Office Action, Claim 23 is objected to under 37 C.F.R. § 1.75(c). In response, Applicants have cancelled Claim 23 without prejudice or disclaimer as previously discussed. Thus, this objection should be rendered moot and therefore withdrawn.

In the Office Action, Claims 1-39 are rejected under 35 U.S.C. § 112, second paragraph. At the outset, the Patent Office alleges that Claim 1 is indefinite as it is unclear what is intended by “a protein source.” Applicants respectfully refer the Patent Office to page 4 at lines 24-26 wherein the Specification discloses that the composition comprises a lipid source, a carbohydrate source and a protein source. A specific example of a protein source according to an embodiment of the present invention is further defined, for example, on page 5 at lines 6-8 where the protein source can include hydrolyzed sweet whey, arginine, tyrosine, and histidine in specified amounts.

Further, the Patent Office alleges that Claim 1 is unclear as to how the different components such as whey, free arginine and free histidine are incorporated therein. As disclosed

on page 2 at lines 11-17, the composition for an infant formula that has a low threonine content includes acid whey protein or sweet whey protein in which caseino-glyco-macropeptide has been removed; free arginine; free histidine; and free tyrosine or tryptophan rich milk protein or free tryptophan or a mixture thereof. As further disclosed in the specification, for example, on page 7 at lines 11-23, the protein source can include free amino acids, such as, L-arginine, L-tryptophan or L-tyrosine, and L-histidine. In view of same, Applicants believe that Claim 1 as presently pending is clear in meaning and scope and thus all other pending claims that recite the same or similar features are clear in meaning and scope as well.

The Patent Office also alleges that the claim term "low threonine content" in Claim 1 is a relative term which renders the claims indefinite. As disclosed in the specification, for example, on page 2 at lines 34-35, the threonine content can be less than about 8g/16gN, more preferably less than about 6g/16gN. Thus, Applicants believe that one skilled in the art should readily understand the scope and meaning of the claim term "low threonine content."

The Patent Office further asserts the claim term "tryptophan rich milk protein" in Claim 1 also has a relative meaning and thus renders the claim indefinite. As disclosed, for example, on page 4 at lines 19-20, tryptophan rich milk protein has a level of about 5% or more of amino acids as tryptophan more preferably about 10% or more. In view of same, Applicants believe that this term should be readily understood by one skilled in the art.

Claim 3 is also rejected as the Patent Office alleges that the claim term "composition comprises about 9.0 to about 10.0 w/w% of protein" is unclear. Indeed, the Specification fully supports this claim term, for example, on page 3 at lines 1-7. The Specification further provides specific compositional examples illustrative of the claimed invention on pages 10-16. Therefore, Applicants believe that one skilled in the art in view of what the Specification discloses would clearly understand the scope and meaning of this term and thus believes that this claim term is clear in scope and meaning.

The Patent Office further rejects Claim 6 as including the claim term "substantially free" which the Patent Office alleges to be relative and thus unclear in meaning. Indeed, this claim term is fully supported in the specification on page 3 at lines 29-31, for example. Thus, Applicants believe that this claim term is clear in meaning as one skilled in the art would readily recognize.

The Patent Office further rejects Claim 10 as allegedly indefinite. In response, Applicants have amended Claim 10. Applicants note for the record that changes made to Claim 10 were made for clarification purposes and thus were not intended to narrow and/or disclaim any claimed subject matter in view of same.

Claim 11 is also rejected as indefinite. The Patent Office alleges that the claim term “comprises a lipid source and carbohydrate source” is unclear. As disclosed in the specification, for example, on page 4 at lines 23-26, the composition includes a lipid source, a carbohydrate source and a protein source. The carbohydrate source is further defined, for example, on page 7 at lines 25-31; and the lipid source is further defined, for example, in the Specification beginning on page 7 at line 33. Thus, Applicants believe that the claim term at issue in Claim 11 is clear in meaning and scope.

Claim 12 has also been rejected as indefinite for use of the claim term “includes.” In response, this claim has been amended. Applicants note for the record that the changes made to Claim 12 should not be deemed as narrowing and/or disclaiming any claimed subject matter in view of same.

Based on at least the reasons stated above, Applicants believe that the pending claims at issue satisfy the requirements of 35 U.S.C. § 112. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claim 18 is rejected under 35 U.S.C. § 103 as being unpatentable over European Patent Document No. 418593A2 (“*Harzer*”). The Patent Office essentially asserts that the cited reference, on its own, discloses or suggests the claimed invention.

Applicants believe that this rejection is improper. Claim 18 recites a method of producing an infant formula composition. The method includes the steps of blending whey protein and casein protein together with free arginine, free histidine, and a component selected from the group consisting of free tyrosine, free tryptophan, tryptophan rich milk protein and mixtures thereof; and homogenizing the blended mixture. Applicants have recognized that by supplementing with the free amino acids, such as arginine, tyrosine and histidine, the protein source has an amino acid profile which is approximate to that of human milk.

Further, the whey protein is selected to provide a lower threonine content that is closer to milk. For example, the whey protein can include an acid whey protein or a sweet whey protein.

Preferably, the sweet whey protein is sweet whey protein from which caseino-glyco-maeropeptide has been removed. This provides the advantage of a reduced threonine content and an increased tryptophan content as compared to normal sweet whey and is therefore suitable as a protein source for infants. See, Specification, p. 3, lines 20-27. Thus, the present invention provides a composition that provides the advantage of mimicking the nutritional benefits of natural human milk for addressing the nutritional needs and providing healthy growth of an infant.

In contrast, Applicants believe that the cited reference is deficient with respect to the claimed invention. The compositions in *Harzer* are described to contain conventional proteins, such as cow milk protein or protein hydrosate and a number of amino acids in specified amounts. In this regard, *Harzer* merely discloses that a protein and/or protein hydrosate can be commonly utilized for preparing an infants formula and that the protein can be supplemented with amino acids in amounts as specified, such as adding threonine to the protein and/or protein hydrosate. Clearly, this suggests that *Harzer* relates to a protein source or composition with a high threonine content unlike the claimed invention. Indeed, threonine is added to or supplements the protein in an amount from 3.62-4.90g/100g total amino acids as disclosed in *Harzer*.

Further, *Harzer* discloses the use of a sweet whey protein source in the examples that is made by precipitating caseins in milk via an enzyme LAB (chymosine). During this precipitation, the k-casein of cows milk is separated into the p-ae-casein and glyco-macropetide wherein the p-ae-casein is precipitated together with the other caseins. However, the glyco-macropetide remains with the sweet whey protein, thus also contributing to the amount of threonine in the composition.

This clearly contrasts the claimed invention. As previously discussed, the claimed invention provides a composition that has an amino acid profile comparable to that of human milk. This is achieved, for example, by supplementing the protein source with free amino acids, such as arginine, tyrosine and histidine as discussed above. The claimed invention provides additional other nutritional benefits. For example, the claimed invention provides a low threonine content, preferably corresponding to 4.9 g per 100 g protein to about 5.1 g per 100g protein as disclosed in the Specification on page 4 at lines 14-17. Thus, the claimed invention

provides the advantage of mimicking the nutritional benefits of natural milk to address nutritional needs and promote healthy growth upon consumption thereof as discussed above. Based on at least these reasons, Applicants believe that the cited reference and the claimed invention are clearly distinguishable. Therefore, Applicants believe that the cited reference fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the forgoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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